K031483

AUG - 1 2003

510(k) Summary – Medrad Manual Syringe Loader

OFFICIAL CONTACT:	Andrew P. Zeltwanger Regulatory Affairs Analyst Medrad, Inc. One Medrad Drive Indianola, PA 15051 (412) 767-2400 ext. 3005
CLASSIFICATION NAME:	Angiographic Injector and Syringe [21 CFR 870.1650]
COMMON NAME:	Syringe Loader
PROPRIETARY NAME(s):	Medrad Manual Syringe Loader
PREDICATE DEVICES:	Spectris Solaris MR Injector System (K012950) Stellant CT Injector System (K023183)
DEVICE DESCRIPTION:	The Medrad Manual Loader is designed as an accessory to Medrad's CT and MR angiographic injectors and syringes. The system offers a manual alternative to the electronic filling function of the injectors. Due to the different configurations of the syringes for the MR and CT injectors, two options of the Manual Loader will be available, each compatible with either CT syringes or MR Syringes.
INTENDED USE:	The Medrad Manual Syringe Loader is designed as an accessory to Medrad's line of angiographic injectors and syringes. It is intended to facilitate manual syringe contrast filling. It is not intended for patient use or use as a contrast injector.

K031483

COMPARISON TO PREDICATE: The Medrad Manual Loader is substantially equivalent to the filling function of the injector head of the Spectris Solaris MR angiographic injector. The Medrad Manual Loader has the same intended use as the syringe filling function of Medrad angiographic injectors.

In the table below, Medrad presents a comparison of the relevant device parameters between the Medrad Manual Loader and the MR/CT Injector Product Line.

Characteristics	**Medrad Manual Loader**	**Stellant CT/Spectris Solaris MR Injectors**
Intended Use	Manual filling of disposable contrast or saline syringes for either CT or MR angiographic injectors	Electro-mechanical filling of disposable contrast/saline syringes and control of delivery of contrast agent to patient during angiographic imaging with CT or MR scanners
Target Population	Medical imaging/Hospital staff	Medical imaging/Hospital staff
Compatibility with Environment and other Devices	Two models available – one compatible with syringes for each imaging modality	Disposable contrast syringes marketed for each injector
MR/CT Compatibility	Not intended to be installed within the scanning rooms	MR hardened for use in the MR environment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

Medrad, Inc.
c/o Andrew P. Zeltwanger
Regulatory Affairs Analyst
One Medrad Drive
Indianola, PA 15051

Re: K031483
Medrad Manual Syringe Loader
Regulation Number: 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: May 9, 2003
Received: July 23, 2003

Dear Mr. Zeltwanger:

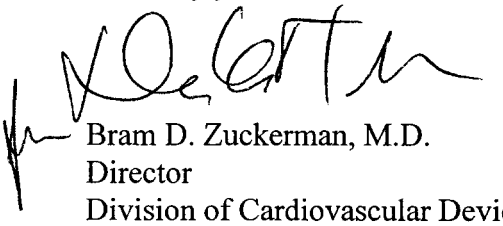
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Intended Use

Indications for Use Statement

510(k) Number: K031483

Device Name: Medrad Manual Syringe Loader

Indications for Use:

The Medrad Manual Syringe Loader is designed as an accessory to Medrad's line of angiographic injectors and syringes. It is intended to facilitate manual syringe contrast filling. It is not intended for patient use or use as a contrast injector.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use ____

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K031483